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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/054,728

10/25/2001

Roberto Fagnani

71726 / 6776

3521

7590

07/05/2006

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/054,728	Applicant(s) FAGNANI ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-18, 31-36 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11-14, 36, 38-40, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 16-18, 31-35 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicants' amendment filed 04/11/2006 and response filed 12/28/2005 are acknowledged and entered.
2. Claims 1-18 and 31-42 were pending. Applicants have amended claims 1, 3, 9, 17, 18, 31-35, 38, and 41; cancelled claims 15 and 37; and added claims 43-45. Therefore, claims 1-14, 16-18, 31-36, and 38-45 are currently pending.

In addition, it is noted that claim 38 has the wrong status identifier since there are markings showing the changes made, i.e. it should be identified as "withdrawn-currently amended". Consequently, applicant is respectfully reminded that any amendment submitted must meets the requirements of 37 C.F.R. 1.121 and see also MPEP § 714.

Election/Restrictions

3. Newly submitted claims 44 and 45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

A) Claims 1-14, 16-18, 31-36, and 38-43 are drawn to a biochip, i.e. product/apparatus.

B) Claims 44 and 45 are drawn to a method of carrying out a biochemical assay.

Inventions of Group A and Group B are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

Art Unit: 1639

product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product such as diagnostic applications, for instance, status of disease condition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44 and 45 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. In addition, it is recognized that the above restriction requirement is between product and process claims. And since applicants have already elected claims directed to the product, and when the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to

Art Unit: 1639

rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant elected the following species for the elected invention (Claims 1-18, and 31-42) in the reply filed on 07/26/2005:

- a. A single specific species of hydrogel cell. Applicant elected *'a hydrogel formed from an isocyanate-functional polymer, more specifically a polymer with urethane linkages, still more specifically a urethane polymer which comprises polyethylene glycol, and yet more specifically one which is the product of a reaction with a polyisocyanate, such as toluene diisocyanate (see page 12, line 33).'* This election is interpreted as a polyethylene glycol that is end-capped with toluene diisocyanate.
- b. A single specific species of binding entity. Applicant elected *'that the binding entity is a protein, and more particularly an immunoglobulin (see page 14, line 11).'*
- c. A single specific species of intermediate agent. *Note: this species was required for the invention of Group II (Claim 18).* Applicant elected telephonically nitrilotriacetic acid found on page 19 line 31 and example 12 (see interview summary). *Note: In the substitute specification, the elected species is found on page 20, line 17.*

Art Unit: 1639

6. Claims 8, 11-14, 36, and 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/26/2005 and phone interview of 10/5/2005.

Priority

7. This instant application claimed the benefit to a provisional application of 60/243, 699 filed 10/26/2000. This instant application is granted the benefit of priority for 60/243,699 under 35 U.S.C 119(e). Additionally, this instant application is a CIP of PCT/US00/11282 filed 04/26/2000, which is a CIP of 09/299,831 filed 04/26/1999.

However, the instant claims 3 and 4 are granted the benefit of priority for PCT/US00/11282 under 35 U.S.C 120, and the instant claims 1, 2, 5, 6, 8 (withdrawn), 15, and 17 are granted the benefit of priority for 09/299,831 under 35 U.S.C 120. Therefore, the effective filing date for claims 1, 2, 5, 6, 8 (withdrawn), 15, and 17 is 04/26/1999, and the effective filing date for claims 3 and 4 is 04/26/2000. The effective filing date for claims 7, 9-14, 18, and 31-42 is 10/26/2000.

8. Claims 1-7, 9, 10, 16-18, 31-35, and 41-43 are under consideration in this Office Action.

Status of Claim(s) Objection(s) and /or Rejection(s)

9. The objection of claims 18 and 41 has been withdrawn in light of applicant's amendments of claims 18 and 41.

Art Unit: 1639

10. The rejection of claims 1-3, 6, 7, 9, 31, 32, 34, and 35 under 35 USC 102(b) as being anticipated by Hartdegen et al. (US Patent 4,098,645) has been withdrawn in view of applicant's amendments of claims 1 and 31.

11. The rejection of claims 1-3, 9, 10, 15, 17, 18, 31, 32, 37, and 41 under 35 USC 102(b) as being anticipated by Sundberg et al. (US Patent 5,624,711) has been withdrawn in view of applicant's amendments of claims 1 and 31 and cancellation of claims 17 and 37.

12. The rejection of claims 1-7, 9, 10, and 15-18 under 35 USC 103(a) being unpatentable over Wagner et al. (US Patent 6,406,921) and Hartdegen et al. (US Patent 4,098,645) has been withdrawn in view of applicant's amendments of claim 1 and cancellation of claim 17.

13. The rejection of claims 31-35, 37, 41, and 42 under 35 USC 103(a) being unpatentable over Sundberg et al. (US Patent 5,624,711) and Hartdegen et al. (US Patent 4,098,645) has been withdrawn in view of applicant's amendments of claim 1 and cancellation of claim 17.

14. The rejection under the judicially created doctrine of obviousness-type double patenting of claims 1-3 and 6 over claims 1, 2, 8, 12, 16, and 26 of U.S. Patent No. 6,174,683 B1 has been withdrawn in view of the terminal disclaimer filed on 12/28/2005.

New Rejection(s) – Necessitated by Amendment

Claim Rejections - 35 USC § 103

Art Unit: 1639

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-7, 9, 10, 16, 17, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg et al. (US Patent 5,624,711) and Braatz et al. (US Patent 5,169,720).

Sundberg et al. disclose derivatized supports with an array of ligands (see e.g. Abstract; col. 1, lines 6-14 and 64-67; col. 2, lines 15-37). The derivatized supports comprise a polymer-coated support (refers to instant claimed solid substrate) and an array of ligands such as peptides (refers to instant claimed binding entity/protein binding entities and instant claim 9)(see e.g. col. 5, lines 25-35; col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 13, lines 46-52). The polymer-coated support comprises a polymer films that provide a porous three-dimensional matrix functionalized with reactive groups, and greater solvent compatibility and flexibility of the reaction site for attachment (see e.g. col. 13, lines 49-60). Accordingly, the polymer films of

Art Unit: 1639

Sundberg et al. is obvious over the instant claimed hydrogel since the definition of the polymer films would encompass the definition of hydrogel as define in the instant specification (see instant specification pg. 10, lines 16-18). The support's surface comprises a diverse array of ligands is produced on the substrate wherein the ligands include polypeptides (refers to instant claimed different binding entity/protein) and predefined regions such as wells to physically separate synthesis regions for different polymers (refers to instant claimed '*discrete locations*')(see e.g. col. 5, line 66 thru col. 6, line 10; col. 6, lines 18-35; col. 11, lines 20-27)(see e.g. col. 5, lines 36-48; col. 6, lines 56-59; col. 9, lines 43-53). The polymer coating includes polyurethanes or polyethylene glycol and isocyanate functional group for the attachment of the ligands (refers to instant claimed isocyanate-functional polymer/urethane linkages, and instant claims 2, 3, 10, 17, and 32)(see e.g. col. 5, lines 25-35; col. 11, lines 59-62). In addition, the ligands can attach to the derivatized supports through a linking molecule (refers to instant claim 10)(see e.g. col. 12, lines 5-16; col. 12, lines 38-41).

The supports of Sundberg et al. differ from the presently claimed invention by failing to include a polymer comprising an isocyanate-capped polyurethane prepolymer and the polyethylene glycol having a molecular weight of at least about 5000.

Braatz et al. disclose polymer-coated devices (see e.g. Abstract; col. 2, lines 46-64; col. 3, lines 20-32). The polymer coatings comprise isocyanate end-capped prepolymer oxyethylene based diols or glycols (see e.g. col. 2, lines 46-64; col. 3, lines 20-32; col. 3, line 43 thru col. 4, line 44). The molecular weight of the oxyethylene based diols or glycols range from 7000 to 30,000 (col. 3, line 43 thru col. 4, line 44; col. 15, line 65 thru col. 16, line 37). The isocyanate include compounds such as toluene diisocyanate (see e.g. col. 5, lines 3-21). The polymer

Art Unit: 1639

coatings are transparent and coated onto a substrate (col. 11, lines 30-34; col. 11, line 64 thru col. 12, line 19). In addition, Braatz et al. disclose that the thickness of the polymer coatings depend on the prepolymer concentration such that the thickness of the polymer coatings substrate would constitute obvious variations in parameters which are routinely modified in the art (see e.g. col. 9, lines 48-59). Thus, the claimed thickness of claims 4, 5, and 33 would be a choice of experimental design and is considered within the purview of the cited prior art of Braatz et al.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a polymer comprising an isocyanate-capped polyurethane prepolymer and the hydrogel having a molecular weight of at least about 5000 as taught by Braatz et al. in the supports of Sundberg et al. One of ordinary skill in the art would have been motivated to include a polymer comprising an isocyanate-capped polyurethane prepolymer and the hydrogel having a molecular weight of at least about 5000 in the supports of Sundberg et al. for the advantage of providing a class of hydrated polymers for which ease of preparation and handling is combined with desirable properties permitting a wide range of end uses (Braatz: col. 2, lines 65-68) since both Sundberg et al. and Braatz et al. disclose a support comprises coated polymers with hydroxyl functional group such as polyethylene glycol (Sundberg: col. 15, lines 21-25; Braatz: col. 4, lines 16-22). In addition, Sundberg et al. disclose that surfaces can be designed and prepared for optimum properties in a particular assay (Sundberg: col. 14, lines 2-6) and as a result the type of polymer use would be a choice of experimental design and is considered within the purview of the cited prior art. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Sundberg et al. and Braatz et al. because Braatz et al. disclosed by example the success of coating surfaces with a polymer

Art Unit: 1639

comprising an isocyanate-capped polyurethane prepolymer (Braatz: col. 19, line 47 thru col. 20, line 54).

Therefore, the combined teachings of Sundberg et al. and Braatz et al. do render the product of the instant claims *prima facie* obvious.

18. Claims 1-7, 9, 10, 16-18, 31-35, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent 6,406,921) and Braatz et al. (US Patent 5,169,720).

Wagner et al. disclose an array of proteins comprising a plurality of patches in discrete, known regions on a substrate, where the protein has different, known sequence is immobilized on each patch and the method of making an array of protein capture agents (see e.g. Abstract; col. 3, lines 26-29; col. 3, lines 44-47; col. 3, lines 56-58; col. 6, lines 45-52; col. 7, lines 17-19; col. 8, lines 10-17). The array comprises of a monolayer (refers to instant claimed hydrogel) on the surface of the substrate and the proteins are immobilized on the monolayer (see e.g. col. 8, lines 10-17; col. 11, lines 15-28 and 39-53). The monolayer comprises the formula of X-R-Y wherein X is the functional group that binds to the surface of the substrate, R is a hydrocarbon chain with the hetero groups such as $-(OCH_2CH_2)_n-$ with $n = 1-20$, and Y is the functional group that binds to the protein such as isocyanate (see e.g. col. 8, lines 10-17; col. 10, lines 10-26; col. 11, lines 15-28 and 39-53). Moreover regarding the claimed thickness of the hydrogel (claims 4, 5, and 37), the thickness of the hydrogel would be a choice of experimental design and is considered within the purview of the cited prior art since Wagner et al. disclose that the monolayer can be of any thickness on the substrate (see e.g. col. 5, lines 15-26). Additionally, the protein can be attached to the Y functional group via an affinity tag (refers to instant claimed

Art Unit: 1639

intermediate agent) or a reagent such as nitrilotriacetic acid (refers to instant claim 43)(see e.g. col. 11, lines 15-28; col. 11, lines 39-46; col. 12, line 59 thru col. 13, line 12). The type of protein includes enzyme and antibodies (see e.g. col. 7, lines 34-47). The substrate comprise patterned such as walls (see e.g. col. 9, lines 55-64).

The support of Wagner et al. differs from the presently claimed invention by failing to a polymer comprising an isocyanate-capped polyurethane prepolymer.

Braatz et al. disclose polymer-coated devices (see e.g. Abstract; col. 2, lines 46-64; col. 3, lines 20-32). The polymer coatings comprise isocyanate end-capped prepolymer oxyethylene based diols or glycols (see e.g. col. 2, lines 46-64; col. 3, lines 20-32; col. 3, line 43 thru col. 4, line 44). The molecular weight of the oxyethylene based diols or glycols range from 7000 to 30,000 (col. 3, line 43 thru col. 4, line 44; col. 15, line 65 thru col. 16, line 37). The isocyanate include compounds such as toluene diisocyanate (see e.g. col. 5, lines 3-21). The polymer coatings are transparent and coated onto a substrate (col. 11, lines 30-34; col. 11, line 64 thru col. 12, line 19). In addition, Braatz et al. disclose that the thickness of the polymer coatings depend on the prepolymer concentration such that the thickness of the polymer coatings substrate would constitute obvious variations in parameters which are routinely modified in the art (see e.g. col. 9, lines 48-59). Thus, the claimed thickness of claims 4, 5, and 33 would be a choice of experimental design and is considered within the purview of the cited prior art of Braatz et al.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to a polymer comprising an isocyanate-capped polyurethane prepolymer as taught by Braatz et al. in the support of Wagner et al. One of ordinary skill in the art would have been motivated to a polymer comprising an isocyanate-capped polyurethane prepolymer in the

Art Unit: 1639

support of Wagner et al. for the advantage of providing a class of hydrated polymers for which ease of preparation and handling is combined with desirable properties permitting a wide range of end uses (Braatz: col. 2, lines 65-68) since both Wagner et al. and Braatz et al. disclose a support comprises coated polymers with hydroxyl functional group such as polyethylene glycol (Wagner: col. 12, lines 31-38; Braatz: col. 4, lines 16-22). In addition, Wagner et al. disclose that there are many possible design choices with regard to the type of coating on the substrate (Wagner: col. 8, lines 34-38) and as a result the type of polymer use would be a choice of experimental design and is considered within the purview of the cited prior art. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Wagner et al. and Braatz et al. because Braatz et al. disclosed by example the success of coating surfaces with a polymer comprising an isocyanate-capped polyurethane prepolymer (Braatz: col. 19, line 47 thru col. 20, line 54).

Thus/Therefore, the combine teachings of Wagner et al. and Braatz et al. do render the product of the instant claims *prima facie* obvious.

Response to Arguments

19. Applicant's arguments with respect to claims 1-7, 9, 10, 16-18, 31-35, and 41-43 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

20. The terminal disclaimer filed on 12/28/2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent

Art Unit: 1639

No. 6,174,683 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T. TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues-Thur: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PETER PARAS, JR can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

mct
June 16, 2006

PETER PARAS, JR.
PRIMARY EXAMINER

Peter Paras Jr.
8PE1639